SECTION 5
510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4454
Fax: 508-683-5939

Contact: Thomas Hirte
Senior Manager, Regulatory Affairs
Date Prepared: March 7, 2014

2. Proposed Device:

Trade Name:	WallFlex™ Biliary RX Stent System
Classification Name:	Catheter, Biliary, Diagnostic
Regulation Number:	876.5010
Product Code:	FGE
Classification:	Class II

3. Predicate Device:

Trade Name:	WallFlex™ Biliary RX Stent System
510(k) Number:	K122072
Classification Name:	Catheter, Biliary, Diagnostic
Regulation Number:	876.5010
Product Code:	FGE
Classification:	Class II

Trade Name:	Advanix Biliary Stent With Naviflex RX Delivery System
510(k) Number:	K101314
Classification Name:	Catheter, Biliary, Diagnostic
Regulation Number:	876.5010
Product Code:	FGE
Classification:	Class II

4. Proposed Device Description:

The WallFlex™ Biliary RX Stent System is an implantable biliary self-expanding metal stent that is pre-loaded onto a Delivery System with a working length of 194mm, which allows delivery of the stent into the Biliary system endoscopically. The self-expanding metal stent consists of Platinum cored Nitinol wires wound together to form a cylinder including flares on both the proximal end and distal end. The WallFlex™ Biliary RX Stent is available uncovered, partially covered, or fully covered with a Permalume™ covering.

5. Indications for Use:
The WallFlex™ Biliary RX Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms, and relief of malignant biliary obstruction prior to surgery.

6. Technological Characteristics:
There are no differences in the technological characteristics between the proposed device and the predicate WallFlex Biliary RX Stent System (K122072). The purpose of this Traditional 510(k) is to request an expanded indication for the proposed WallFlex™ Biliary RX Stent System. The physical devices will remain unchanged from the predicate K122072, but the expanded indication requires a change to the product labeling. All other design specifications remain unchanged.

7. Performance Data:
No performance data was required for this submission.

Boston Scientific used published clinical results of stents used for pre-operative biliary drainage. The conclusion from this review demonstrates that the WallFlex Biliary Stent System can be safely and effectively used as a relief of biliary obstruction prior to surgery.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed WallFlex™ Biliary RX Stent System can be safely and effectively used for its proposed expanded indication.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 23, 2014

Boston Scientific
Thomas Hirte
Sr. Manager, Regulatory Affairs
100 Boston Scientific Way
Marlborough, MA 01752

Re: K140630
Trade/Device Name: WallFlex™ Biliary RX Stent System
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE
Dated: April 1, 2014
Received: April 2, 2014

Dear Thomas Hirte,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christy L. Foreman -S

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):	K140630
Device Name:	WallFlex™ Biliary RX Stent System
Indications For Use:	The WallFlex™ Biliary RX Stents are indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms and relief of malignant biliary obstruction prior to surgery.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
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